

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,)
)
Plaintiff,)
) C.A. No. 23-975-RGA
v.)
)
LIQUIDIA TECHNOLOGIES, INC.,)
)
Defendant.)

J. Caleb Boggs Courthouse
844 North King Street
Wilmington, Delaware

Monday, September 30, 2024
9:02 a.m.
Markman Hearing

BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: MICHAEL J. FLYNN, ESQUIRE

-and-

GOODWIN LAW FIRM
BY: WILLIAM JACKSON, ESQUIRE
BY: ERIC ROMEO, ESQUIRE

-and-

McDERMOTT WILL & EMERY
BY: ART DYKHUIS, ESQUIRE
BY: DOUGLAS H. CARSTEN, ESQUIRE
BY: ADAM W. BURROWBRIDGE, ESQUIRE
BY: JAKE B. VALLEN, ESQUIRE

For the Plaintiff

1 APPEARANCES CONTINUED:

2 SHAW KELLER LLP
3 BY: KAREN E. KELLER, ESQUIRE

4 -and-

5 COOLEY LLP
6 BY: SANYA SUKDUANG, ESQUIRE
7 BY: JONATHAN DAVIES, ESQUIRE
BY: JOHN HABIBI, ESQUIRE
BY: RACHEL PRESTON, ESQUIRE
BY: ROSALYND UPTON, ESQUIRE

08:49:23 8 For the Defendant

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09:02:22

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*** PROCEEDINGS ***

09:02:22 11

DEPUTY CLERK: All rise.

09:02:30 12

THE COURT: All right. Good morning, everyone.

09:02:33 13

So we've got a Markman in *United Therapeutics*

09:02:37 14

vs. Liquidia, which is Civil Action Number 23-975. Everyone

09:02:41 15

can be seated.

09:02:42 16

Mr. Flynn.

09:02:43 17

MR. FLYNN: Good morning, Your Honor. Michael

09:02:48 18

Flynn from Morris Nichols on behalf of United Therapeutics.

09:02:51 19

At counsel table is William Jackson and Eric Romeo from

09:02:55 20

Goodwin. Art Dykhuis and Adam Burrowbridge from McDermott.

09:02:58 21

And in the back we have Doug Carsten and Jake Vallen of

09:02:58 22

McDermott Will & Emery.

09:03:03 23

Mr. Dykhuis, I believe, will do the first term

09:03:06 24

today.

09:03:07 25

THE COURT: All right. Ms. Keller.

09:03:10 1 MS. KELLER: Good morning, Your Honor. Karen
09:03:14 2 Keller from Shaw Keller on behalf of the Defendant. With me
09:03:16 3 today, Sanya Sukduang, Jonathan Davies and Rosalynd Upton,
09:03:21 4 all from Cooley. Also, Rachel Preston and John Habibi from
09:03:25 5 Cooley. And Russ Schundler from Liquidia.

09:03:28 6 THE COURT: All right. Well, good morning to
09:03:29 7 everyone.

09:03:31 8 So we've got three terms. Before we start, can
09:03:35 9 someone just tell me where we are generally?

09:03:40 10 And by that, I mean, I denied a preliminary
09:03:46 11 injunction some time ago, but as I recall or right about the
09:03:49 12 same time that I denied it or afterwards, something
09:03:53 13 happened. Maybe the FDA did something that means that the
09:03:59 14 Defendant is not likely to be launching real soon.

09:04:06 15 Can someone tell me about that?

09:04:08 16 MR. SUKDUANG: Yes, Your Honor. So I think
09:04:11 17 there are two FDA things going on. So when you denied your
09:04:14 18 PI motion, UTC had simultaneously brought an action, an APA
09:04:20 19 action in the District of Delaware.

09:04:22 20 THE COURT: District of Columbia?

09:04:23 21 MR. SUKDUANG: Yeah, District of Columbia also
09:04:25 22 seeking a PI. The District of Columbia denied that PI.
09:04:29 23 Then recently, I believe in August or early September of
09:04:33 24 this year, the FDA granted United Therapeutics additional
09:04:43 25 exclusivity for their dry powder which will run until May of

09:04:48 1 2025.

09:04:49 2 THE COURT: Oh, okay.

09:04:50 3 MR. SUKDUANG: And so because of that, Liquidia
09:04:54 4 cannot launch their product until at least May of 2025.
09:05:00 5 Based on that, Liquidia filed its own APA action in the
09:05:03 6 District of Columbia. Summary judgment briefing on the
09:05:09 7 propriety of the exclusivity is being briefed and summary
09:05:14 8 judgment argument will be in December of 2024.

09:05:18 9 THE COURT: And you say "the propriety," is it
09:05:21 10 the case that Liquidia's saying it should be longer or it's
09:05:24 11 the case that United Therapeutics is saying it shouldn't be,
09:05:28 12 I guess, at all?

09:05:29 13 MR. SUKDUANG: No, so flipped. So Liquidia is
09:05:31 14 saying there should be no exclusivity granted to UTC so it
09:05:35 15 should be able to launch.

09:05:36 16 THE COURT: Oh.

09:05:37 17 MR. SUKDUANG: And UTC and the FDA is trying to
09:05:39 18 defend that position. So depending on the outcome of
09:05:42 19 summary judgment, in December, before the District of
09:05:47 20 Columbia, UTC -- Liquidia may be able to launch before May
09:05:50 21 or we may be stuck until May.

09:05:52 22 THE COURT: All right. But, in any event, the
09:05:58 23 way things are kind of teed up right now, the District Court
09:06:03 24 in the District of Columbia who's basically the agent who's
09:06:07 25 going to -- agent is not the right word, but the judge

09:06:11 1 that's going to decide something that, if necessary, or, you
09:06:15 2 know, if there needs to be immediate action, it's going to
09:06:18 3 be because of something the judge there does --

09:06:20 4 MR. SUKDUANG: Yes.

09:06:21 5 THE COURT: -- at least up until May of 2025.

09:06:23 6 MR. SUKDUANG: Up until May of 2025. And
09:06:26 7 whether UTC tries to renew, I don't think the factors have
09:06:29 8 changed. But, again, we'll have to wait until December.

09:06:32 9 THE COURT: Okay. All right.

09:06:33 10 Thank you. All right.

09:06:34 11 So we've got these three terms. I assume we're
09:06:38 12 going to do them in the same order they show up in the
09:06:40 13 briefing?

09:06:42 14 MR. DYKHUIS: Yes, Your Honor.

09:06:46 15 THE COURT: And first off, remind me who you
09:06:48 16 are.

09:06:49 17 MR. DYKHUIS: Art Dykhuis with McDermott.

09:06:54 18 THE COURT: All right. So I was curious in
09:06:57 19 terms of the first term here, in the Plaintiff's proposed
09:07:13 20 construction, you say, to the extent it needs to be
09:07:17 21 construed, it is "one or more, unless context clearly
09:07:21 22 dictates otherwise."

09:07:23 23 Where in the claims does the context clearly
09:07:26 24 dictate otherwise?

09:07:28 25 MR. DYKHUIS: Where -- well, Your Honor, there's

09:07:31 1 a few different places. And the --

09:07:35 2 MR. JACKSON: May I?

09:07:36 3 MR. DYKHUIS: Your Honor, may we approach with
09:07:38 4 some slides?

09:07:40 5 THE COURT: Oh, yeah. Sure.

09:07:47 6 MR. DYKHUIS: So there's a few -- I'll directly
09:07:49 7 answer the Court's question. There is a couple examples
09:07:51 8 that come to mind when you asked where does context dictate
09:07:54 9 otherwise. And if we could actually have Slide 4.

09:08:00 10 This is Claim 1. "A" and "the" shows up
09:08:04 11 throughout Claim 1 and throughout the dependent claims 50,
09:08:08 12 60 instances. Just in Claim 1, you have in the parties'
09:08:13 13 briefing, it addresses a patient. So by administration to
09:08:16 14 the patient having pulmonary hypertension -- excuse me. A
09:08:20 15 patient and then the patient. So if the scope -- if an
09:08:25 16 embodiment is being mapped to the claims in some way for
09:08:27 17 infringement or invalidity, and it's pointing at a single
09:08:31 18 patient, then the patient would have to match that. So the
09:08:33 19 context would dictate if you're looking at -- if you're
09:08:37 20 evaluating one patient, the patient would refer back to that
09:08:39 21 one patient.

09:08:41 22 Another example would be a maximum tolerated
09:08:44 23 dose. In context it seems to make sense that a patient
09:08:47 24 would have a one maximum tolerated dose versus some plural
09:08:50 25 set of maximum tolerated doses.

09:08:52 1 THE COURT: So I'm not sure. What I understand
09:08:55 2 you're saying is let's just talk about "a" or "and" first.

09:09:02 3 MR. DYKHUIS: Okay.

09:09:02 4 THE COURT: Is there any place where "a" or
09:09:04 5 "and" does not mean one or more?

09:09:06 6 MR. DYKHUIS: The one example I just gave, Your
09:09:12 7 Honor, maximum tolerated dose, I think there it would be one
09:09:14 8 that the patient would have a maximum tolerated dose.
09:09:17 9 Another example would be that Claim 1 itself is a method and
09:09:20 10 it's defining the outer bounds of a method.

09:09:23 11 Those are the two examples that come to mind,
09:09:25 12 Your Honor. And the point --

09:09:27 13 THE COURT: All right. Well, so is it -- it
09:09:30 14 says -- I forget how many claims there are, but I think
09:09:33 15 there's something like --

09:09:33 16 MR. DYKHUIS: Sixteen.

09:09:34 17 THE COURT: -- 19?

09:09:35 18 MR. DYKHUIS: I believe 16.

09:09:36 19 THE COURT: How many?

09:09:39 20 MR. DYKHUIS: I've got a copy of the patent
09:09:41 21 right here.

09:09:42 22 THE COURT: So do I.

09:09:43 23 MR. DYKHUIS: Nineteen.

09:09:44 24 THE COURT: Yes. Are all 19 asserted?

09:09:46 25 MR. DYKHUIS: I think all except for Claim 13,

09:09:48 1 Your Honor.

09:09:48 2 THE COURT: Okay. Not a nebulizer.

09:09:52 3 All right. Well, when we're through today, I
09:09:58 4 would like you to point out to me -- I would like you-all to
09:10:06 5 write a letter that basically identifies in the 18 asserted
09:10:11 6 claims every place where "a" does not mean one or more.

09:10:18 7 All right?

09:10:18 8 MR. DYKHUIS: We can do that, Your Honor.

09:10:20 9 THE COURT: Okay. And then whatever -- all
09:10:29 10 right.

09:10:30 11 In terms of the -- do you agree that the
09:10:34 12 patent -- there's an attempt at lexicography here?

09:10:40 13 MR. DYKHUIS: That is right. I think you're
09:10:42 14 thinking of Column 6.

09:10:44 15 THE COURT: Right. And when I say "an attempt
09:10:48 16 at lexicography," there is lexicography. Maybe there's a
09:10:53 17 question about how good lexicography it is, but definitely
09:10:58 18 the patentee's, when we're talking about "a" and "the" are
09:11:02 19 attempting to be lexicographers; right?

09:11:05 20 MR. DYKHUIS: I believe so. That's right, Your
09:11:07 21 Honor.

09:11:07 22 THE COURT: Okay. The phrase "includes plural
09:11:10 23 referents, unless the context clearly dictates otherwise,"
09:11:14 24 let's skip the "unless the context clearly dictates
09:11:18 25 otherwise." "Includes plural referents," is that just a

09:11:27 1 strange patent lawyer way of saying one or more?

09:11:30 2 MR. DYKHUIS: Yes, Your Honor.

09:11:31 3 THE COURT: Okay. All right.

09:11:33 4 Well, I don't think right now I need to -- so
09:11:38 5 actually let me just go -- I've got one other question for
09:11:41 6 you, I think.

09:11:42 7 So what does Claim 2 -- where it says, "The
09:11:53 8 method of Claim 1, wherein said administering provides a
09:11:56 9 statistically significant increase of a six-minute walk
09:12:00 10 distance in the patient after 8 weeks, 12 weeks or
09:12:03 11 16 weeks," I take it the after 8 weeks, 12 weeks or 16 weeks
09:12:09 12 means any one of the three will do?

09:12:13 13 MR. DYKHUIS: Yes, Your Honor.

09:12:14 14 THE COURT: Okay. So what does -- providing "a
09:12:20 15 statistically significant increase of a six-minute walk
09:12:24 16 distance," how do you determine that?

09:12:29 17 MR. DYKHUIS: Your Honor, I believe you -- well,
09:12:34 18 you look at the data for the method that's being used. And
09:12:39 19 what we have in the patent is it describes individual
09:12:42 20 patients being treated, of course, but also clinical studies
09:12:44 21 that were conducted. Specifically looking at this
09:12:47 22 indication, the PH-ILD indication and following the regimen
09:12:51 23 that's in Claim 1.

09:12:52 24 And so what you can look at for Claim 2 and what
09:12:55 25 we did at the PI stage is analyze: What data do we have?

09:13:01 1 And you can look back at the data that's in the patent, for
09:13:04 2 example, and it describes statistically significant results
09:13:07 3 at those time points.

09:13:08 4 THE COURT: So I haven't gone back to look at
09:13:10 5 the patent for that, but in Claim 3, it talks about an
09:13:13 6 increase of what I believe is 20 meters. 10M, whatever M
09:13:17 7 is --

09:13:18 8 MR. DYKHUIS: Right.

09:13:19 9 THE COURT: -- after eight weeks. So does that
09:13:22 10 mean that if you do this method with a patient and that
09:13:26 11 particular patient can walk 11 meters after eight weeks, it
09:13:30 12 falls within the claim? But if the patient can only walk
09:13:33 13 nine meters, it doesn't, all other things being equal?

09:13:38 14 MR. DYKHUIS: All other things being equal?

09:13:42 15 THE COURT: In other words, don't argue with me
09:13:43 16 about, well, 12 weeks, 16 weeks.

09:13:46 17 MR. DYKHUIS: Oh, sure.

09:13:47 18 THE COURT: Sorry.

09:13:47 19 MR. DYKHUIS: What I would say, Your Honor, is
09:13:51 20 if there are -- I'm searching for the right table. It's
09:13:55 21 Table 5 or 6, but, in essence, there's data in the patent
09:13:59 22 that reflects the statistically significant results. And
09:14:02 23 the average results in different forms of data for the
09:14:05 24 patients that were in the study that was conducted and
09:14:08 25 described in the specification.

09:14:09 1 And really when Claim 2 and these other claims
09:14:13 2 are referring back, they reference the administering in the
09:14:16 3 method of Claim 1. And so the question is: For a given --
09:14:20 4 obviously, candidly, Liquidia is, of course, intending to
09:14:25 5 sell their product to one patient or multiple patients. And
09:14:27 6 when those patients follow the method that's in Claim 1,
09:14:30 7 that would be infringing.

09:14:31 8 And necessarily we would have to ask: What do
09:14:33 9 we know about the method that, for example, Liquidia will be
09:14:37 10 using? We know the characteristics of that method are that
09:14:40 11 it will provide a statistically significant increase after
09:14:43 12 six -- of a six-minute walk distance. It will provide an
09:14:46 13 increase of --

09:14:47 14 THE COURT: Well --

09:14:48 15 MR. DYKHUIS: -- for the average patient.

09:14:50 16 THE COURT: -- let's say we know that because of
09:14:52 17 what you've got in the rest of the patent. How does proving
09:14:55 18 Claim 2 differ from proving Claim 1?

09:14:58 19 MR. DYKHUIS: I'm not sure if I understand the
09:15:05 20 Court's question.

09:15:06 21 THE COURT: Well, okay. So there's a narrowing
09:15:10 22 because it's a dependent claim. What part of -- what in
09:15:16 23 Claim 1 is now not part of Claim 2?

09:15:19 24 MR. DYKHUIS: It -- well, I'm going to state the
09:15:24 25 obvious, but I'm not trying to be dense about this. So as

09:15:30 1 you mentioned, Your Honor, the -- Claim 2 does narrow. It
09:15:33 2 could be -- it's not the case here. It could be that
09:15:35 3 somebody develops a different drug and they do their own
09:15:39 4 clinical studies. It may be those clinical studies show
09:15:43 5 that actually their product, for whatever reason, is
09:15:44 6 ineffective. It doesn't provide a statistically significant
09:15:47 7 increase. Maybe there's no statistical significance or
09:15:50 8 there was no improvement numerically whatsoever --

09:15:53 9 THE COURT: So --

09:15:54 10 MR. DYKHUIS: -- that --

09:15:54 11 THE COURT: -- Claim 2 is essentially adding in
09:15:59 12 it has passed FDA, I don't know, standards for getting a
09:16:03 13 drug?

09:16:04 14 MR. DYKHUIS: I don't see FDA specifically
09:16:07 15 there, but certainly it would require statistical
09:16:09 16 significance which implicates, of course, a clinical study
09:16:12 17 of some sort.

09:16:13 18 THE COURT: But does Claim 2 require that you
09:16:16 19 prove -- basically your reading of Claim 2 is it means sort
09:16:22 20 of Claim 1, and there's a clinical study that shows Claim 1
09:16:31 21 will do claim -- the add-on of Claim 2?

09:16:35 22 MR. DYKHUIS: If I -- yes. Yes, Your Honor.
09:16:38 23 That's my understanding.

09:16:39 24 THE COURT: Okay. And, roughly speaking, Claims
09:16:44 25 2 and 3 sort of parallel each other except that, I guess, 10

09:16:50 1 meters is a rounded-off number from whatever is
09:16:54 2 statistically significant. But how do Claims 2 and 3 differ
09:16:59 3 from each other?

09:17:01 4 MR. DYKHUIS: Just in terms of I think their
09:17:06 5 words, Your Honor. I don't know. I'd have to page back
09:17:09 6 through the patent and find out how it's statistically
09:17:12 7 significant.

09:17:12 8 THE COURT: But is Claims 2 and 3 -- I guess
09:17:18 9 what I'm wondering is: Does Claim 3 depend on what happens
09:17:22 10 to the particular patient to whom the method is
09:17:25 11 administered, but Claim 2 does not?

09:17:29 12 MR. DYKHUIS: It -- Claim 2 -- I think the
09:17:34 13 answer to that is, yes, Your Honor. The Claim 2 recites the
09:17:36 14 statistical significant increase. And I think we can look
09:17:40 15 at a study for that. And that's how it was addressed at the
09:17:42 16 PI stage.

09:17:43 17 Claim 3, excuse me, I think you can do one of
09:17:47 18 two ways. You could look at the patient. Did they get that
09:17:53 19 increase?

09:17:53 20 But you could also look at the clinical trial
09:17:56 21 data and see: What do we know about the product that's
09:17:59 22 being administered according to this method?

09:18:01 23 THE COURT: So you administer the method to a
09:18:05 24 patient. And instead of increasing how much they can walk,
09:18:10 25 they don't. But you're saying that still meets Claim 3

09:18:16 1 because you can prove it by statistics?

09:18:19 2 MR. DYKHUIS: Certainly for Claim 2, it does. I
09:18:21 3 think that would be an option for Claim 3, yes, because what
09:18:25 4 we're looking at, the patent is describing a clinical study
09:18:28 5 and data. And it's claiming a method of treatment. And
09:18:32 6 clinical studies always reflect this, Your Honor, that not
09:18:36 7 every single patient necessarily will get exactly the same
09:18:39 8 benefit. And so certainly patients, for one reason or
09:18:43 9 another, will have varying degrees in success from the
09:18:46 10 treatment.

09:18:46 11 THE COURT: But Claim 3, I think, claims that
09:18:49 12 the patient does get this benefit, not some other guy out
09:18:53 13 there who was part of a clinical trial. It's talking about
09:18:56 14 the patient who got the treatment, isn't it?

09:19:00 15 MR. DYKHUIS: This is another time where I just
09:19:04 16 have to apologize, Your Honor. I'm not sure I followed that
09:19:06 17 question.

09:19:07 18 THE COURT: Okay. Well, so it says, "The method
09:19:11 19 of Claim 1 wherein," blah, blah, blah, the patient increases
09:19:19 20 the walk distance by the recited amount.

09:19:22 21 MR. DYKHUIS: Right.

09:19:23 22 THE COURT: You're saying that you could be
09:19:25 23 treating a patient who doesn't increase by the recited
09:19:30 24 amount, and yet they still meet the limitations because some
09:19:35 25 other people in the clinical trial did meet the recited

09:19:39 1 amount?

09:19:41 2 MR. DYKHUIS: What the -- I'm trying to make,
09:19:43 3 Your Honor, and I'm answering the question as directly as I
09:19:46 4 can. The point is some -- these claims have no requirement
09:19:50 5 that after the method is performed that a doctor perform
09:19:55 6 measurements.

09:19:55 7 THE COURT: I didn't say -- I mean, yeah. Okay.

09:20:00 8 MR. DYKHUIS: And if I may, so the point there
09:20:03 9 is there's no requirement to go out and measure individual
09:20:06 10 patients each time. We can still analyze infringement
09:20:10 11 because we're able to look at, Okay, what are the
09:20:12 12 characteristics and the output from a clinical study which
09:20:16 13 we know has been conducted and reflects the results of the
09:20:21 14 method that's claimed in Claim 1?

09:20:22 15 And in this instance, Your Honor, we know that
09:20:25 16 Liquidia, for example, is relying on UTC's clinical data to
09:20:29 17 support its own application. So, in essence, the results
09:20:33 18 that we have at issue here that show statistical
09:20:36 19 significance, that show increases in six-minute walk
09:20:38 20 distance is the very same data that describes Liquidia's
09:20:43 21 products, at least as it represents to the FDA.

09:20:45 22 THE COURT: So if the -- let's assume, for the
09:20:52 23 sake of argument, the statistically significant increase in
09:20:55 24 your clinical trials was 10 meters. If that were the case,
09:21:00 25 then Claims 2 and 3 would be exactly the same?

09:21:05 1 MR. DYKHUIS: I don't read Claim 2 and Claim 3
09:21:14 2 as exactly the same.

09:21:15 3 THE COURT: Well, so listen to my hypothetical.
09:21:18 4 How would it be different if the statistically significant
09:21:20 5 increase was 10 meters?

09:21:23 6 MR. DYKHUIS: Well, number one, Your Honor,
09:21:27 7 it -- the statistical significance is a limitation in and of
09:21:33 8 itself. So within Claim 3, if there's no statistical
09:21:37 9 significance in whatever data that is being analyzed, you
09:21:41 10 could point to data that didn't show statistical
09:21:44 11 significance, I believe, for three, but not for two. At
09:21:47 12 least the statistical significance as an explicit limitation
09:21:50 13 in two.

09:21:51 14 And just to put it in context. Claim 1 is a
09:21:54 15 method of improving exercise capacity. So that's a
09:21:57 16 broader -- Claim 2 is the specific increase in six-minute
09:22:02 17 walk distance. But it's a statistically significant
09:22:05 18 increase, whereas in Claim 3 it's an increase in that
09:22:09 19 specific measure of exercise capacity, six-minute walk
09:22:12 20 distance. And it puts a specific number on it, 10 meters,
09:22:15 21 and could be -- depending on the data you're looking at, the
09:22:18 22 10 meters is the statistically significant number or it
09:22:21 23 could be a different number.

09:22:22 24 THE COURT: Right. No. I understand that that
09:22:25 25 is -- that's the reason I was asking. You assume that it

09:22:26 1 was the statistically significant number.

09:22:32 2 Okay. All right. Let me hear from the other
09:22:34 3 side.

09:22:34 4 MR. DYKHUIS: Thank you, Your Honor.

09:22:36 5 THE COURT: Thank you.

09:22:37 6 MR. SUKDUANG: Your Honor, I think

09:22:37 7 Mr. Dykhuis --

09:22:51 8 MR. DAVIES: Your Honor, may I approach with
09:22:52 9 binders?

09:22:53 10 THE COURT: Sure. Yes.

09:22:54 11 MR. SUKDUANG: I'm sorry. I think Mr. Dykhuis'
09:22:59 12 attempted explanation to your questions evidences the
09:23:02 13 problems with the claim. Claim 1 requires an improvement in
09:23:10 14 exercise capacity. Claim 2 -- so that could be done with a
09:23:15 15 single patient.

09:23:17 16 Claim 2 depends from Claim 1 and requires a
09:23:21 17 statistical significant change. You cannot do that with a
09:23:24 18 single patient. And what UTC is trying to do is use written
09:23:28 19 description support, which is a validity issue, and
09:23:31 20 enablement, and use that to say a single patient by Liquidia
09:23:35 21 will prove infringement.

09:23:36 22 You can't -- our label doesn't do that. It
09:23:39 23 doesn't instruct taking the "data," as UTC just
09:23:43 24 acknowledged, and extrapolate its statistical significance.
09:23:47 25 So Claim 2 requires multiple patients collecting the data

09:23:53 1 and determining whether there's statistical significance.

09:23:57 2 Claim 3 doesn't depend from Claim 1. It doesn't
09:24:01 3 depend from Claim 2. It depends from Claim 1.

09:24:04 4 Claim 3 says if you look at the patient in Claim
09:24:07 5 1 and you're improving exercise capacity, by what measure do
09:24:12 6 I assess that? Claim 3 says you look at six-minute walk and
09:24:17 7 you improve it by 10 meters.

09:24:19 8 So the difference between the claims goes back
09:24:21 9 to the optional language that UTC is trying to include with
09:24:25 10 the or. They want to establish infringement of the
09:24:30 11 statistically significant claims by pointing to a single
09:24:35 12 patient by Liquidia.

09:24:36 13 But then for invalidity, they're going to
09:24:39 14 require Liquidia to prove that a single patient is not
09:24:45 15 enough. And we've seen that already in the PI context. In
09:24:49 16 the PI context, Liquidia -- UTC argued, and it's their
09:24:54 17 declarant, Dr. Nathan, DI-28 at Paragraphs 209 and 211. It
09:24:59 18 says you need a clinical trial to prove invalidity
09:25:04 19 reasonable expectation of success.

09:25:05 20 They argued -- UTC argued itself, DI-26 -- this
09:25:08 21 is their opening PI brief at Pages 12 to 13 -- that you need
09:25:12 22 a clinical trial to prove invalidity reasonable expectation
09:25:17 23 of success. If that's the case for the statistical
09:25:20 24 significant claims, then that has to be the construction for
09:25:25 25 infringement because you cannot construe Claim 2 permitting

09:25:30 1 infringement by a single patient and then requiring for
09:25:34 2 invalidity Liquidia to prove multiple patients. And that is
09:25:39 3 the fundamental problem that we see with the "one or more."

09:25:43 4 On the issue of "one or more," most of the cases
09:25:48 5 or actually all of the cases that UTC cites, including the
09:25:51 6 *Azurity* case, the Defendant, like Liquidia, tries to limit
09:25:56 7 "a" to a single buffer, a single person, a single something,
09:26:00 8 not more than a single. We're not trying to do that. We're
09:26:04 9 actually trying to give meaning to "a," and "the" and "and"
09:26:07 10 when you look at Claim 1, and you look at Claim 2 and you
09:26:10 11 look at all the statistical significant claims which require
09:26:14 12 more.

09:26:14 13 You asked Mr. Dykhuis: How do you figure out
09:26:20 14 the statistical significant part of Claim 2? And the
09:26:25 15 specification tells you that. I'm at Slide 8 of our slides,
09:26:28 16 but it's Column 31.

09:26:30 17 UTC argued in their reply brief that Claim 2 can
09:26:34 18 be proven by a single patient, that you don't need multiple
09:26:38 19 patients to prove a statistical significance. That's wrong.
09:26:42 20 The specification teaches you at Slide -- Page 31 that in
09:26:46 21 order to determine, in order to provide written description
09:26:50 22 and enablement support for those claims, the study had to
09:26:55 23 have -- had to be powered sufficiently enough to run a
09:26:58 24 statistical analysis. And for the six-minute walk test,
09:27:02 25 they used a mixed model measurement. That's a statistical

09:27:06 1 analysis.

09:27:06 2 You cannot infringe with a single patient. When
09:27:10 3 you look at the dependent claims, the secondary endpoints
09:27:14 4 like NT-proBNP of FDC, the specification tells you that if
09:27:19 5 the primary endpoint is met, which is six-minute walk, you
09:27:23 6 have to -- you can look at the secondary endpoints, these
09:27:26 7 dependent claims. And they, too, used a statistical
09:27:30 8 analysis, the hierarchal testing procedure.

09:27:32 9 Our fundamental issue and the reason why we
09:27:37 10 believe our construction is correct, and I understand the
09:27:40 11 proclivity with "one or more," is that the specification
09:27:46 12 specifically says "includes," "includes plural" "unless the
09:27:53 13 context dictates otherwise."

09:27:55 14 What UTC is trying to do is take "the context
09:27:57 15 dictates otherwise" and make that the rule when that is the
09:28:01 16 exception. The exception is the "or." And there is nothing
09:28:05 17 in the specification that UTC points to that calls it
09:28:09 18 optionally. The lexicography that they used doesn't use
09:28:13 19 optional language. And when you look at the claims as a
09:28:16 20 whole and trying to construe these claims consistently
09:28:20 21 between Claim 1 and Claim 2, and I'm at Slide 7 here, the
09:28:25 22 "or" -- "and more" is required for the statistical
09:28:31 23 significance, not the "or."

09:28:33 24 And what UTC is going to do, and again, we've
09:28:37 25 seen it already and Mr. Dykhuis just confirmed it today,

09:28:39 1 they want to take a single patient that Liquidia may treat
09:28:45 2 or a doctor may treat and say because that single patient
09:28:49 3 may fall into what a clinical trial was done under control
09:28:53 4 conditions years earlier, you automatically infringe.

09:28:56 5 That is not the case. The issue is whether our
09:29:00 6 label -- and these are all method claims -- whether our
09:29:01 7 label instructs, induces, suggests to doctors to treat
09:29:08 8 someone with inhaled treprostinil so that individuals get a
09:29:14 9 statistically significant change. We do not do that.

09:29:20 10 They're trying to avoid that outcome by pointing
09:29:23 11 to the "or" optional language. Our construction comports
09:29:27 12 with the claims as a whole and the express language in the
09:29:31 13 specification about include, not optionally.

09:29:35 14 So I've tried to address those issues. You
09:29:39 15 probably have questions for me, maybe not. The "unless" --
09:29:44 16 or "unless the context dictates otherwise," we don't think
09:29:48 17 that should be a part of the construction because that's the
09:29:50 18 exception, not the rule.

09:29:51 19 UTC wants to make it the rule. And there's
09:29:54 20 nothing in the claims that dictates otherwise.

09:29:57 21 THE COURT: All right. Thank you.

09:30:00 22 Okay. Well, I'm done.

09:30:10 23 MR. SUKDUANG: Oh, okay. I thought you had
09:30:12 24 something else.

09:30:12 25 THE COURT: No. That's okay.

09:30:18 1 All right. Well, so we've got lexicography
09:30:20 2 here, and it says the singular forms and -- and "the include
09:30:27 3 plural referents, unless the context clearly dictates
09:30:30 4 otherwise." I take that to be, as I said, lexicography.
09:30:36 5 And I take it that the way of saying one or more, "unless
09:30:50 6 the context clearly dictates otherwise."

09:30:53 7 So I am going to construe it as being one or
09:30:56 8 more. But I think the "unless the context dictates
09:31:01 9 otherwise" leaves too much wiggle room in for the Plaintiff,
09:31:10 10 which is the reason why I want a letter where they say for
09:31:19 11 "a," "and," and "the," where the context clearly dictates
09:31:24 12 otherwise, and when they have that, what the otherwise is.
09:31:31 13 Presumably from context, it's that it's singular.

09:31:38 14 And so I don't understand this to be, you
09:31:42 15 know -- so the claims, they've got to be construed one way
09:31:48 16 or the other. You know, how that applies to invalidity,
09:31:52 17 infringement, that's an issue for another day.

09:31:55 18 So maybe by the end of this week, Mr. Dykhuis,
09:32:03 19 you can submit a letter that for every claim other than 13
09:32:10 20 states what it is. So that at the end of the day, the
09:32:14 21 construction will not be "one or more unless the context
09:32:19 22 dictates otherwise" because we'll know which ones the
09:32:23 23 context dictates otherwise. So it will be fixed.

09:32:26 24 Okay?

09:32:26 25 MR. DYKHUIS: Understood. Thank you.

09:32:28 1 THE COURT: All right.

09:32:29 2 MR. SUKDUANG: Your Honor, just a clarification.
09:32:32 3 Do you want both parties to submit by the end of the week or
09:32:35 4 just UTC? And do we get to respond?

09:32:37 5 THE COURT: Well, if they submit something and
09:32:39 6 you want to respond, that's fine. You know, I just want
09:32:42 7 to -- and it may be that -- but I would like to know what
09:32:47 8 their view is. And so in the context or in the -- with the
09:32:53 9 understanding that basically it is one or more, you know,
09:33:00 10 you can indicate, after they've done it, where you think
09:33:03 11 the -- where they have indicated the context wrongly. Okay?
09:33:07 12 And maybe I'll address that now or maybe I'll address that
09:33:12 13 somewhere down the road.

09:33:13 14 All right. So let's go on to "maximum tolerated
09:33:16 15 dose."

09:33:18 16 And actually, given the fact that this is an
09:33:27 17 indefiniteness argument, why don't I hear from the Defendant
09:33:30 18 first.

09:33:32 19 MR. BURROWBRIDGE: Yes, Your Honor.

09:33:38 20 THE COURT: So my first question, because I will
09:33:41 21 have some questions for you is: Don't you think any medical
09:33:48 22 professional understands the concept of "maximum tolerated
09:33:51 23 dose"? Isn't that something that is, I don't know, well
09:33:56 24 understood in the medical field?

09:33:58 25 MR. SUKDUANG: I think in the abstract, yes,

09:34:01 1 Your Honor. But when you look at the claims, the claims are
09:34:03 2 written in a particular way here. So --

09:34:06 3 THE COURT: So let's just follow that in the
09:34:09 4 abstract. Would you say "maximum tolerated dose" is
09:34:13 5 essentially a term of art in the medical field that doctors,
09:34:21 6 persons of ordinary skill in the art would understand?

09:34:23 7 MR. SUKDUANG: I think we can agree that in the
09:34:26 8 abstract outside this patent, a "maximum tolerated dose"
09:34:30 9 could be understood by a doctor.

09:34:32 10 THE COURT: Okay. And would you say it's a term
09:34:36 11 of art or is it not even that complex? Because --

09:34:40 12 MR. SUKDUANG: I'm not sure it's a term of art
09:34:42 13 because I'm not sure doctors use "maximum tolerated dose."
09:34:47 14 I think when you look at labels, it just says titrate up or
09:34:51 15 it tells you what the maximum dose is, like you can only go
09:34:55 16 to 400 milligrams or whatever it might be. But I agree with
09:35:01 17 your original premise.

09:35:03 18 THE COURT: Okay. All right.

09:35:04 19 So with that being the case, you have some
09:35:08 20 burden here to show that they've deviated from that meaning.
09:35:14 21 And so why don't you go ahead and try to persuade me.

09:35:18 22 MR. SUKDUANG: Sure. I understand and we
09:35:19 23 understand that the burden on us is clear and convincing.
09:35:22 24 It's an invalidity argument with indefiniteness.

09:35:24 25 Outside the context, as we talked about, a

09:35:26 1 doctor might understand that a patient might understand
09:35:28 2 that, but you have to look at "maximum tolerated dose" in
09:35:31 3 the context of these claims.

09:35:33 4 Claim 1 requires improving exercise capacity.
09:35:38 5 That is one outcome for treatment. Okay. Claim 2, Claim 5,
09:35:45 6 Claim 6, Claim 9 depend directly from Claim 1. They require
09:35:50 7 a different outcome measure.

09:35:52 8 Claim 5 is a good example. NT-proBNP, right.
09:35:57 9 So Claim 5 depends from Claim 1. In order to meet -- fall
09:36:02 10 within the scope of Claim 5, the patient has to first have
09:36:06 11 improved exercise capacity. And then, in addition to
09:36:11 12 improved exercise capacity, they have to have a reduction in
09:36:17 13 NT-proBNP. That means from baseline that value has to look
09:36:21 14 negative or decreased. Two separate, distinct measured
09:36:26 15 outcomes based on a "maximum tolerated dose."

09:36:29 16 The problem with the specification, the problem
09:36:32 17 with the claims and why it's indefinite is because there is
09:36:37 18 no clarity or certainty within the specification as to
09:36:41 19 which -- if I don't meet one, which outcome dictates
09:36:46 20 "maximum tolerated dose."

09:36:48 21 And I want to go to the examples, Table 5.
09:36:53 22 Well, first, when you look at the specification, the maximum
09:36:56 23 dose that patients were given is 72 micrograms at week 16.

09:37:00 24 Okay. When you look at Table 5, all of the
09:37:03 25 patients at week 16 had improved six-minute walk. That is

09:37:08 1 the improved exercise capacity of Claim 1.

09:37:12 2 Okay. But at that same time point, 16 weeks,
09:37:17 3 when you look at that second measurement, NT-proBNP, and
09:37:21 4 that's Claim 5, some patients improved. That's the negative
09:37:25 5 number.

09:37:26 6 But other patients, their NT-proBNP got worse.
09:37:30 7 That's the positive, 5, 3, 7, 3. Right.

09:37:34 8 So you're supposed to see from baseline. If
09:37:36 9 you're improving, if you're meeting Claim 5, it should be
09:37:40 10 less than what you were at baseline, the negative numbers.
09:37:43 11 If you're worsening, you're getting the positive numbers and
09:37:47 12 that's what we've outlined in the red box.

09:37:49 13 The conflict and the indefiniteness comes from
09:37:52 14 this exact outcome. If I meet Claim 1 at 72 micrograms, and
09:37:59 15 I have improved exercise capacity, that same patient has
09:38:06 16 worsening NT-proBNP at that same dose. Which outcome
09:38:11 17 measured dictates the "maximum tolerated dose"? The
09:38:15 18 specification does not tell you that.

09:38:18 19 And there's two different ways within Claim 5 to
09:38:23 20 assess "maximum tolerated dose." Do I look at exercise
09:38:28 21 capacity, because I have to meet that for Claim 1, or do I
09:38:32 22 look at NT-proBNP, because that's a requirement from Claim
09:38:36 23 5? A doctor, a patient, a skilled artisan does not have
09:38:43 24 reasonable certainty, based on the specification itself, as
09:38:48 25 to which measurement I use.

09:38:50 1 And that's like the *Teva* case. That was
09:38:52 2 molecular weight, and you can measure molecular weight three
09:38:55 3 different ways.

09:38:56 4 That is analogous to what the specification of
09:38:58 5 the '327 teaches. It can measure outcomes based on
09:39:02 6 administration and the "maximum tolerated dose" in multiple
09:39:06 7 different ways.

09:39:06 8 And if I go back to the claims, you can look at
09:39:09 9 exercise capacity for Claim 1. All of the dependent claims
09:39:14 10 require exercise capacity. Claim 2, you can look at it as a
09:39:18 11 six-minute walk test. Claim 5, you can look at it
09:39:20 12 separately as NT-proBNP. Claim 6, you can look at an
09:39:24 13 exacerbation of interstitial lung disease. Or Claim 9, an
09:39:29 14 improvement in FEC.

09:39:31 15 These are not the same outcomes. They are not
09:39:34 16 the same measurements. And there is no indication that if I
09:39:38 17 hit the "maximum tolerated dose" for Claim 1 that I'm going
09:39:43 18 to improve any of these dependent claims with that "maximum
09:39:48 19 tolerated dose."

09:39:48 20 And if I have to increase the "maximum tolerated
09:39:52 21 dose" to meet this NT-proBNP, then I might fail the exercise
09:39:57 22 capacity. That patient might withdraw.

09:40:00 23 When you look at the definition of "maximum
09:40:02 24 tolerated dose," there is none in the specification. But
09:40:06 25 it's used twice. Once when discussing therapeutically

09:40:10 1 effective, and therapeutic effective is disease progression
09:40:15 2 onset, delaying onset of symptoms. "Maximum tolerated dose"
09:40:19 3 is also addressed in functional improvement like the
09:40:22 4 six-minute walk test.

09:40:23 5 Those two issues don't align. How do we see
09:40:26 6 that? Again, the specification tells you that they are
09:40:30 7 different outcome measures that lead to different results
09:40:33 8 based on the same dose.

09:40:35 9 Figure 4 is the six-minute walk again at weeks
09:40:38 10 4, 8, 12 and 16. Claim 1, you get that improvement. You
09:40:42 11 don't need statistical significance in Claim 1.

09:40:45 12 Figure 2, people discontinued treprostinil
09:40:49 13 therapy because of disease progression. How do those two
09:40:53 14 align? Whether you're looking at a functional improvement,
09:40:56 15 which is one usage of "maximum tolerated dose" versus
09:41:00 16 disease progression, there is another use of "maximum
09:41:05 17 tolerated dose." That is the lack of certainty within the
09:41:08 18 claims.

09:41:08 19 Again, when you're looking at "maximum tolerated
09:41:15 20 dose," if the specification or the claims were written as
09:41:24 21 independent claims, each of them independent, we wouldn't
09:41:27 22 have this argument because you could just look at exercise
09:41:31 23 capacity. Yes. Or you can look at NT-proBNP by itself,
09:41:34 24 independent of exercise capacity. Yes.

09:41:37 25 The problem comes from how the claims are

09:41:40 1 written where they all depend from Claim 1. And when you
09:41:44 2 look at the dependent claims, two independent and unrelated
09:41:50 3 outcomes need to be achieved. And the specification teaches
09:41:53 4 you that with the maximum dose, you don't necessarily get
09:41:58 5 that double outcome with the doses given.

09:42:01 6 That is the basis for invalidity. That is the
09:42:05 7 basis for indefiniteness.

09:42:06 8 I won't cover, unless you want me to, our
09:42:10 9 alternative construction, but that is our basis.

09:42:12 10 THE COURT: So doesn't "maximum tolerated dose"
09:42:21 11 refer to the amount that the patient is given, not relative
09:42:31 12 to outcomes that it's designed to be treating for, but you
09:42:41 13 know, essentially when side effects or, you know, it starts
09:42:48 14 to have some negative consequences for the patient?

09:42:52 15 MR. SUKDUANG: No, not within the claims because
09:42:54 16 the claims -- it's a method claim. You have to treat this
09:42:57 17 patient.

09:43:00 18 THE COURT: So let's assume the "maximum
09:43:01 19 tolerated dose" before the patient overdoses is 10 grams or
09:43:07 20 10 micrograms. If it improves lung capacity or exercise
09:43:14 21 capacity, you've proved that prong. If you also prove
09:43:22 22 reduction of NT-proBNP, then you've proved a dependent
09:43:27 23 claim.

09:43:27 24 If you don't prove the reduction of NT-proBNP,
09:43:32 25 well then you haven't proved the dependent claim, but you

09:43:36 1 still proved the independent claim. And, of course, if you
09:43:39 2 don't improve exercise capacity, then you haven't proved
09:43:42 3 anything. I mean, you don't meet any claims.

09:43:44 4 MR. SUKDUANG: Right, right. But the issue is
09:43:46 5 you have to have a max -- the claim requires a "maximum
09:43:49 6 tolerated dose." So you have to -- you have -- the way the
09:43:53 7 specification reads, and we heard this with respect to "a"
09:43:59 8 and "the," the studies done in the patent were not, Let's
09:44:05 9 just dose the people until we see an improvement. The
09:44:09 10 specification and the examples were, Let's give them the
09:44:13 11 maximum dose and assess the various improvements.

09:44:18 12 And so you have to go through. And the way this
09:44:21 13 disease works, it's a progressive disease. Patients are
09:44:27 14 going to have to take more and more of the drug over time
09:44:30 15 because their disease is going to get worse and worse and
09:44:33 16 worse. That's the therapeutically effective part. You want
09:44:36 17 to delay disease progression.

09:44:38 18 So a patient starts on at 50 micrograms and
09:44:41 19 feels good. Then you start seeing things gets worse. You
09:44:44 20 increase the dose and you see things getting worse and
09:44:46 21 increase the dose.

09:44:48 22 At some point that patient may have improved
09:44:52 23 exercise capacity, but no NT-proBNP improvement. Or vice
09:44:57 24 versa, you start seeing improvement in one of these other
09:44:59 25 functions, but then they can't tolerate the drug.

09:45:04 1 And so that's the lack of certainty. Where do I
09:45:09 2 go when I look at what is required by the claims; right?
09:45:16 3 Again, I come back to the issue of infringement and
09:45:20 4 validity. UTC is going to say you need to prove all these
09:45:23 5 things --

09:45:23 6 THE COURT: All right. You know, I've heard
09:45:25 7 enough. I don't think it's indefiniteness. You know, I
09:45:27 8 think "maximum tolerated dose" is essentially independent of
09:45:33 9 whether the thing works or not. And it's going to be the
09:45:38 10 same for one patient. It's going to be the same no matter
09:45:42 11 what measurement of improved, you know, exercise capacity or
09:45:51 12 reduction is in NT-proBNP you're talking about.

09:45:58 13 So I'm not going to find that this is indefinite
09:46:02 14 by clear and convincing evidence. And I don't actually
09:46:07 15 think it needs to be construed.

09:46:12 16 All right?

09:46:12 17 MR. SUKDUANG: Okay. Thank you, Your Honor.

09:46:13 18 THE COURT: All right. Is there anything
09:46:15 19 Plaintiff wants to say?

09:46:18 20 MR. DYKHUIS: No, Your Honor. Thank you.

09:46:20 21 THE COURT: All right. Let's go on to "pulsed
09:46:26 22 inhalation device."

09:46:30 23 All right. You're Mr. Carsten; right?

09:46:31 24 MR. JACKSON: I'm Mr. Jackson. Thank you. I'm
09:46:34 25 honored to be confused with Mr. Carsten, but I'm

09:46:37 1 Mr. Jackson.

09:46:37 2 THE COURT: Okay. Sorry about that.

09:46:39 3 MR. JACKSON: All good. Thank you.

09:46:41 4 So may it please the Court. Here's the -- here
09:46:47 5 are the two parties' constructions.

09:46:49 6 THE COURT: Right.

09:46:50 7 MR. JACKSON: Our construction is "device that
09:46:52 8 provides for non-continuous inhaled drug delivery." Theirs
09:46:56 9 is "a device that provides the force for non-continuous drug
09:47:00 10 delivery." So it's literally the same except the words "the
09:47:03 11 force."

09:47:04 12 So the ultimate question here is: Where does
09:47:08 13 the force have to come from? Any pulse -- you've got a
09:47:12 14 pulse in your veins right now. Your heart's doing that. A
09:47:17 15 wave is a pulse of water. There are lots of things that are
09:47:19 16 pulses. There has to be some force to create that pulse.
09:47:23 17 It could be wind, gravity, a difference in pressure,
09:47:27 18 whatever, but there has to be something that creates a
09:47:30 19 pulse.

09:47:30 20 Their construction requires that pulse to come
09:47:32 21 only from the device. That is an incorrect construction
09:47:37 22 on -- this is a sort of summary of where we're going, but
09:47:39 23 let me walk you through.

09:47:40 24 These are the claims. "Pulsed inhalation
09:47:44 25 device," and it says 14 is -- "a pulse inhalation device is

09:47:48 1 a dry powder inhaler."

09:47:49 2 THE COURT: And excuse me a second, Mr. Jackson.

09:47:53 3 So the "pulsed inhalation device" has nothing to do with

09:47:57 4 Claims 1 to 10; right?

09:48:01 5 MR. JACKSON: With the exception of 1 -- 11

09:48:04 6 depends on 1.

09:48:07 7 THE COURT: Right. But, I mean, 1 to 10,

09:48:12 8 there's no -- this dispute is irrelevant to Claims 1

09:48:18 9 through 10; right?

09:48:18 10 MR. JACKSON: Correct. Correct.

09:48:19 11 THE COURT: Okay. But then does it apply to all

09:48:26 12 the rest of the claims?

09:48:27 13 MR. JACKSON: Again, with the exception of 13

09:48:29 14 which --

09:48:29 15 THE COURT: Right, because that's out of the

09:48:31 16 case.

09:48:31 17 MR. JACKSON: Can I have the patent?

09:48:33 18 MR. DYKHUIS: Yeah.

09:48:38 19 THE COURT: So I'm guessing it doesn't really

09:48:40 20 apply to Claims 15 and on. All it really applies to is

09:48:51 21 Claims 11, 12 and 14; right?

09:48:52 22 MR. JACKSON: Correct, Your Honor.

09:48:53 23 THE COURT: Okay. Thank you.

09:48:54 24 MR. JACKSON: Yeah. So we know that the "pulsed
09:48:56 25 inhalation device" is a dry powder inhaler. So let's look

09:49:01 1 at what the specification says about "pulsed inhalation
09:49:03 2 device" and dry powder inhalers.

09:49:05 3 THE COURT: Wait. Hold on a minute.

09:49:08 4 So in Claim 14, it's a dry powder inhaler, but
09:49:13 5 it's not a dry powder -- it's not limited to a dry powder
09:49:18 6 inhaler in Claims 11 and 12.

09:49:21 7 MR. JACKSON: Correct, Your Honor.

09:49:23 8 THE COURT: Okay. So, I'm sorry. Go ahead.

09:49:36 9 MR. JACKSON: Yeah. So we know that the "pulsed
09:49:41 10 inhalation device" includes dry powder inhalers. Right.
09:49:45 11 Claim 14 says "the pulsed inhalation device."

09:49:47 12 THE COURT: It can certainly include some dry
09:49:50 13 powder inhalers.

09:49:51 14 MR. JACKSON: Sure. Not all. Not all.

09:49:52 15 THE COURT: Right.

09:49:53 16 MR. JACKSON: It doesn't have to be all. All
09:49:54 17 I'm asking for is some dry powder inhalers.

09:49:57 18 THE COURT: Yes.

09:49:58 19 MR. JACKSON: So let's look at what the
09:50:00 20 specification says. So this is at Column 21, Lines 6
09:50:03 21 through 14. The first line says, "The inhalation device,
09:50:05 22 such as a pulsed inhalation device, may be a dry powder
09:50:07 23 inhaler." Again, so we know that the pulsed inhalation
09:50:11 24 device may be a dry powder inhaler.

09:50:14 25 In that same paragraph, at the bottom of the

09:50:17 1 paragraph, it says, "For example, a dry powder inhaler and
09:50:20 2 dry powder composition or formulation can be found in
09:50:26 3 *Guarneri*." That's what that reference is.

09:50:28 4 THE COURT: Okay.

09:50:28 5 MR. JACKSON: So let's see what *Guarneri* says.
09:50:31 6 This is *Guarneri*. *Guarneri* is a -- involves a dry powder
09:50:35 7 inhaler that is a breath-powered inhaler. So the force
09:50:39 8 comes from the breath.

09:50:41 9 When you're -- when the question about whether
09:50:43 10 the force -- the way the force has to come from, this
09:50:46 11 answers that question. *Guarneri* says the -- which is
09:50:49 12 referenced again and incorporated into the patent -- the dry
09:50:53 13 powder inhaler is a breath-powered inhaler.

09:50:58 14 THE COURT: And a dry powder inhaler, is that
09:51:13 15 basically just referring to the fact that it's using dry
09:51:19 16 powder as opposed to a gas, or a liquid or something else?

09:51:25 17 MR. JACKSON: Yes, yes. So you can breathe in a
09:51:27 18 mist. You can breathe in -- lots of kids have asthma, and
09:51:31 19 they have that little meter-dosed inhaler. You squeeze it
09:51:34 20 and it shoots a little mist into your mouth.

09:51:36 21 THE COURT: Right. The thing you're talking
09:51:38 22 about where you squeeze it, that is that force; right?

09:51:41 23 MR. JACKSON: That has its own force, and it's
09:51:43 24 compressed air, right, that you squeeze.

09:51:45 25 THE COURT: Right.

09:51:45 1 MR. JACKSON: Correct.

09:51:46 2 THE COURT: Right.

09:51:46 3 MR. JACKSON: So that's an example that has the
09:51:48 4 power inside it. Correct.

09:51:49 5 THE COURT: Right. But getting to a dry powder
09:51:51 6 inhaler, what that would involve is very fine granules of
09:51:56 7 something?

09:51:56 8 MR. JACKSON: Correct.

09:51:57 9 THE COURT: And so a dry powder inhaler could be
09:52:02 10 something where you have a device that supplies the force or
09:52:06 11 it could be something where, for example, breaths of the
09:52:10 12 human supplies the force?

09:52:11 13 MR. JACKSON: Correct, Your Honor.

09:52:12 14 THE COURT: And are there other options?

09:52:15 15 MR. JACKSON: I can -- I think, since you've got
09:52:17 16 a device and you've got a device and a -- it's either
09:52:20 17 supplied by the device or by the human. Like I don't know
09:52:23 18 any other options.

09:52:24 19 THE COURT: Okay. All right.

09:52:26 20 MR. JACKSON: No. I think -- it's a good
09:52:28 21 question. I like it totally. And there are --

09:52:31 22 THE COURT: You like totally random questions?

09:52:34 23 MR. JACKSON: Well, I would have been trying to
09:52:36 24 think through like the differences that -- there's
09:52:39 25 continuous and there's pulsed. Those are the two

09:52:42 1 distinctions, right.

09:52:43 2 The continuous is like the cannula that people
09:52:46 3 have for the oxygen over there and then through their nose,
09:52:48 4 and they're continuously breathing. Or you've got a
09:52:51 5 respirator that you're continuously breathing through.

09:52:54 6 THE COURT: Okay.

09:52:54 7 MR. JACKSON: Right. That's a continuous or
09:52:56 8 it's pulsed. It's delivered in pulses like a wave. Like
09:52:58 9 a --

09:52:58 10 THE COURT: And does pulsed refer to, you know,
09:53:04 11 you do it as needed, or you do it every two hours or that
09:53:08 12 kind of thing as opposed to --

09:53:11 13 MR. JACKSON: Yes, Your Honor, constant
09:53:14 14 infusion.

09:53:14 15 THE COURT: Like with the forced one that you
09:53:16 16 squeeze one, wait a second, squeeze another?

09:53:19 17 MR. JACKSON: Well, each of those would be a
09:53:21 18 pulse. It's the continuous. It's -- the distinction is
09:53:24 19 between pulsed and continuous, right.

09:53:26 20 So a continuous is you're always on it. It's
09:53:28 21 like those cannulas.

09:53:29 22 THE COURT: So the cannula, would that be
09:53:31 23 pulsed?

09:53:31 24 MR. JACKSON: No, that's continuous. You're
09:53:33 25 just breathing it in through your nose and it's continually

09:53:36 1 driving.

09:53:36 2 THE COURT: So pulsed is --

09:53:38 3 MR. JACKSON: Pulsed is like a bolus of -- like
09:53:39 4 you're taking a shot of something. Like it's a pulse of --

09:53:45 5 THE COURT: Right.

09:53:46 6 MR. JACKSON: -- the medication.

09:53:46 7 THE COURT: Right. So, and that got to -- I
09:53:48 8 think this was in the briefing some -- pulsed essentially
09:53:52 9 means non-continuous. That's the reason why both sides have
09:53:56 10 non-continuous in their construction.

09:53:59 11 MR. JACKSON: Yes, Your Honor. All right.

09:54:02 12 So, again, *Guarneri*, a cite referenced in the
09:54:05 13 patent as an example of a dry powder inhaler. And we know
09:54:10 14 *Guarneri* is breath-powered. So we know that the force does
09:54:12 15 not come from the device, it comes from the person.

09:54:15 16 THE COURT: And so *Guarneri*, that's actually
09:54:17 17 prior art to this?

09:54:18 18 MR. JACKSON: Yes.

09:54:18 19 THE COURT: Okay. And I guess in a way it makes
09:54:28 20 sense that if you have fine enough grains of whatever it is
09:54:32 21 you're inhaling, that you can -- that a person could just
09:54:41 22 breathe it in and get it far enough up their nose or
09:54:44 23 possibly mouth.

09:54:48 24 Inhaler, does that mean through the nose?

09:54:50 25 MR. JACKSON: I think it means through the

09:54:51 1 mouth. I think it's inhaled. I mean, I guess it could be,
09:54:55 2 in theory, through the nose. The example that everybody's
09:54:59 3 talking about, all the examples here are through the mouth
09:55:02 4 into the lungs. It's being pulled down into the lungs.

09:55:04 5 THE COURT: Okay. All right. Okay.

09:55:08 6 MR. JACKSON: And, again, the focus of the
09:55:10 7 difference is whether the device has to perform the force.

09:55:14 8 THE COURT: Right. And so I think in the
09:55:15 9 briefing, and you can help me out here by going through
09:55:17 10 these things, besides for *Guarneri*, there were other places
09:55:20 11 where you said the embodiments describe or there's reference
09:55:28 12 that shows it covers dry powder inhalers; right?

09:55:32 13 MR. JACKSON: Yes. So my next example is
09:55:36 14 also -- this is also in the patent. "Inhaled compositions
09:55:39 15 may include dry powder compositions." And then on the
09:55:43 16 bottom line it says -- it has a reference. It discloses
09:55:46 17 "which are incorporated by reference." That's for *Roscigno*.

09:55:50 18 Here is *Roscigno*. That is, again, it allows the
09:55:54 19 cap -- that's a device that you squeeze. It allows the
09:55:57 20 capsule to spin -- the centrifugal force drives the powder
09:56:03 21 out and then you breathe it in. So that's another example
09:56:05 22 of a breath-powered, inhaled, pulsed --

09:56:10 23 THE COURT: Well, the "centrifugal force," does
09:56:16 24 that help -- I mean, is that a force -- is the device
09:56:27 25 there -- isn't the device there providing some of the force?

09:56:30 1 MR. JACKSON: So the device pierces the little
09:56:34 2 capsule and then spins it to pull the powder out of the
09:56:38 3 capsule. But it's still in your -- it's at the other end of
09:56:42 4 the pipes where those two little pipes are, right.

09:56:44 5 THE COURT: Okay.

09:56:45 6 MR. JACKSON: And you have to suck it in so
09:56:47 7 you're breathing it in through --

09:56:47 8 THE COURT: So it's more like -- the way --
09:56:51 9 maybe this is a bad analogy, but it's more like the things
09:56:56 10 we're talking about. The centrifugal puncture, that's kind
09:56:59 11 of like opening the package.

09:57:01 12 MR. JACKSON: Correct.

09:57:01 13 THE COURT: And then the delivery of the package
09:57:03 14 is through breathing.

09:57:04 15 MR. JACKSON: Correct, Your Honor. So, again,
09:57:07 16 referenced in the patent, and this is, in fact, the device
09:57:10 17 that Liquidia's product uses.

09:57:14 18 Here's another figure in the patent. This is
09:57:18 19 the one that you can see was used for the safety evaluation,
09:57:23 20 the safety study. So that's our device, Figure 11. That is
09:57:28 21 a breath-powered device, right.

09:57:30 22 So we have a picture of a breath-powered device
09:57:33 23 in the patent itself. The force from that device does not
09:57:36 24 come from the device itself. It comes from the patient
09:57:38 25 breathing it in through that removable mouthpiece cover or

09:57:42 1 the white mouthpiece.

09:57:43 2 THE COURT: And I'm sorry to interrupt you with
09:57:46 3 another random question. What's the priority date of this
09:57:49 4 patent? I don't need the exact, but what year are we
09:57:57 5 talking about; do you think?

09:57:58 6 MR. JACKSON: So I think it was -- the
09:57:59 7 provisional was filed in 2020.

09:58:01 8 THE COURT: Okay. All right.
09:58:04 9 Sorry. Go ahead.

09:58:05 10 MR. JACKSON: So these are the three things
09:58:08 11 referenced. These are the three dry powder inhalers.
09:58:11 12 Again, we know dry powder inhalers are among pulsed
09:58:14 13 inhalation devices.

09:58:15 14 These are the three dry powder inhalers
09:58:17 15 referenced or pictured in the patent itself. Every one of
09:58:22 16 them is breath-powered. Every one of them falls within the
09:58:27 17 circle on the left, dry powder inhalers disclosed in the
09:58:31 18 patent.

09:58:32 19 Liquidia's construction would require the dry
09:58:35 20 powder inhalers to be powered by the device. Nothing, no
09:58:39 21 dry powder inhalers are disclosed -- that are powered by the
09:58:42 22 device are disclosed in the patent. That cannot be the
09:58:46 23 right construction.

09:58:48 24 Liquidia instead focuses on nebulizers. And
09:58:52 25 nebulizers are like blowing a mist to you. And there's lots

09:58:57 1 of nebulizers out there, including several that are
09:58:59 2 referenced in the patent. And those can be, I don't
09:59:02 3 necessarily think always are, but can be powered devices.
09:59:06 4 So the force can come from the device.

09:59:09 5 And I'll agree that the force can come from the
09:59:11 6 device. It just doesn't have to come from the device. It
09:59:14 7 can also come from the person.

09:59:16 8 They focus -- they want the Court to focus on
09:59:18 9 nebulizers which are powered not on dry powder inhaled
09:59:23 10 devices. No dry powder inhalers fit Liquidia's definition.

09:59:30 11 THE COURT: And the reason why Claim 13 is not
09:59:34 12 in the case is because the nebulizer is a mist and
09:59:39 13 presumably their ANDA is claiming some kind of dry powder;
09:59:42 14 right?

09:59:43 15 MR. JACKSON: Correct.

09:59:43 16 THE COURT: Okay.

09:59:44 17 MR. JACKSON: In fact, that's -- their dry
09:59:46 18 powder is this dry powder. It is exactly this.

09:59:52 19 All right. So no -- none of their -- the dry
09:59:58 20 powder inhalers is referenced in the patent or of which I'm
10:00:00 21 aware fit their definition. In fact, when we asked in the
10:00:04 22 preliminary injunction proceedings, asked their expert,
10:00:05 23 using their definition: Have you ever encountered a pulsed
10:00:10 24 inhalation device based on that the device has to supply the
10:00:13 25 power that is also a dry powder inhaler? "No, not in my

10:00:16 1 experience."

10:00:16 2 So their expert isn't even aware of the
10:00:19 3 existence of such a dry powder inhaler. So it may --

10:00:24 4 THE COURT: So just go back to that for a
10:00:26 5 second. And yet the claim here is the pulsed inhalation
10:00:34 6 device is a dry powder inhaler.

10:00:37 7 MR. JACKSON: Correct. He's using their
10:00:38 8 definition of the device has to drive -- has to -- the force
10:00:42 9 has to come from the device.

10:00:44 10 THE COURT: Oh, wait. Hold on.

10:00:46 11 So he's using their definition when he says it's
10:00:55 12 a device that delivers a pulse?

10:00:57 13 MR. JACKSON: Correct.

10:00:57 14 THE COURT: But "delivers," wouldn't you use
10:01:01 15 that terminology if you were breathing it in?

10:01:06 16 MR. JACKSON: So the thing I've highlighted in
10:01:09 17 the three dots is about 12 lines long that elaborates, yes,
10:01:14 18 I'm using the -- in essence, I'm using their definition. It
10:01:17 19 would have been way too much to -- like I hate words on
10:01:20 20 slides. I try to limit words on slides.

10:01:22 21 THE COURT: Well, we're in agreement on words on
10:01:24 22 slides, but it's like you left out the trick in the Jack in
10:01:29 23 the Box.

10:01:30 24 MR. JACKSON: Sorry.

10:01:32 25 THE COURT: All right. Well, go ahead.

10:01:33 1 MR. JACKSON: But so, again, this is what's
10:01:35 2 disclosed in the patent. None of them fit in their
10:01:38 3 construction. It just can't. The intrinsic evidence, you
10:01:41 4 can't.

10:01:42 5 THE COURT: Okay. So I got these -- I got what
10:01:44 6 you're saying about these three. I appreciate what you've
10:01:46 7 said.

10:01:47 8 You had maybe other things you wanted to say?

10:01:50 9 MR. JACKSON: Yeah. So I've already -- it's --
10:01:55 10 our definition is consistent with the specification. It's
10:01:59 11 consistent with those three examples, and it distinguishes
10:02:02 12 things, whether they are pulsed.

10:02:04 13 Their definition imports limits outside the
10:02:08 14 specification. There's nothing in the specification about
10:02:10 15 it being powered. Excludes embodiments in the
10:02:13 16 specification. Includes those examples. Encompasses the
10:02:16 17 device that Liquidia's expert admits doesn't exist. And
10:02:19 18 focuses on nebulizers, not dry powder inhalers. And
10:02:22 19 distinguishes based on whether they're powered not whether
10:02:25 20 they're -- whether they are powered or not, not whether
10:02:27 21 they're pulsed.

10:02:28 22 So this was the summary slide that kind of
10:02:30 23 covered all the other pieces of --

10:02:32 24 THE COURT: Okay. You know, I didn't -- because
10:02:34 25 there were too many words, I didn't read it all the first

10:02:37 1 time around. And there seemed like a lot of lines, but now
10:02:40 2 I see the exemplary embodiments are taking up most of the
10:02:43 3 space there, though it's consistent with the specification.
10:02:47 4 I also saw that. And I get the last bullet point.

10:02:52 5 So unless you have something more, why don't I
10:02:54 6 hear from your opponent. And, you know, this one I may
10:03:02 7 easily -- I'll give you a chance to respond to whatever he
10:03:06 8 says.

10:03:06 9 Okay?

10:03:07 10 MR. JACKSON: Thank you, Your Honor.

10:03:10 11 THE COURT: Are you Mr. -- is it Davies or
10:03:13 12 Davis?

10:03:13 13 MR. DAVIES: Davies, Your Honor.

10:03:14 14 THE COURT: Davies, all right. Go ahead,
10:03:18 15 Mr. Davies.

10:03:19 16 MR. DAVIES: Sorry. I think, as my friend
10:03:39 17 indicated, the dispute between the parties is: Where does
10:03:41 18 the pulse come from? And we think that our construction, in
10:03:45 19 accordance with the plain and ordinary meaning, makes clear
10:03:47 20 that the pulse is coming from the device, that it is a
10:03:50 21 pulsed inhalation device. And that it's not, for example, a
10:03:53 22 pulsed patient who's using an unpulsed device.

10:03:57 23 So our construction --

10:03:58 24 THE COURT: So --

10:03:59 25 MR. DAVIES: Yes.

10:04:00 1 THE COURT: -- one of the things that
10:04:04 2 Mr. Jackson said, and I think maybe there was something in
10:04:09 3 the briefing that indicates you think differently, but he
10:04:13 4 says -- he didn't maybe specifically say this, but I
10:04:16 5 understand his position to be that people of ordinary skill
10:04:20 6 in the art understand pulsed is as opposed to continuous.

10:04:28 7 Do you agree with that?

10:04:29 8 MR. DAVIES: There is continuous, Your Honor.
10:04:30 9 We would classify those as respirators. They're also not a
10:04:34 10 pulsed inhalation device because they're not pulsed in any
10:04:38 11 way.

10:04:38 12 THE COURT: Right, right, right. I think he'd
10:04:39 13 agree that they're not pulsed inhalation devices.

10:04:42 14 MR. SUKDUANG: Correct.

10:04:43 15 THE COURT: But in other words, it's the use of
10:04:44 16 the word "pulsed" where, you know, my understanding of what
10:04:51 17 Mr. Jackson said was, as opposed to, you know, what a layman
10:04:57 18 might think is you have continuous and non-continuous. And
10:05:00 19 those are opposites or at least different.

10:05:04 20 What he says is you have pulsed and you have
10:05:07 21 non-continuous and they're different. Do you agree with
10:05:10 22 that?

10:05:11 23 MR. DAVIES: I agree that there is a difference
10:05:12 24 between pulsed and non-continuous. But within pulsed, you
10:05:16 25 have those that are non-continuous and breath-powered. I'm

10:05:20 1 sorry. Within pulsed, you have to have force. So if it's a
10:05:26 2 non-continuous device like a dry powder inhaler like what is
10:05:29 3 used in Liquidia's product, that is breath-powered. So by
10:05:33 4 adding in the force, we are distinguishing between the two
10:05:36 5 types of inhalation devices that are non-continuous.

10:05:40 6 THE COURT: So how do you get around the
10:05:42 7 references in the specification to the "pulsed inhalation
10:05:50 8 devices" including things that appear to be non-pulsed
10:05:53 9 according to your or -- you know, that involve no force
10:05:58 10 according to -- how do you address that?

10:06:02 11 MR. DAVIES: So if you look at Slide 26, I
10:06:04 12 think, of Mr. Jackson's presentation, he pointed to three
10:06:07 13 pieces of evidence.

10:06:08 14 THE COURT: Yes.

10:06:09 15 MR. DAVIES: The first was *Guarneri* which is
10:06:11 16 incorporated. If we -- and we will look at this. But when
10:06:14 17 you look at how *Guarneri* is incorporated into the patent,
10:06:17 18 it's incorporated for its disclosure of dry powder inhalers
10:06:20 19 and powder compositions. It is not incorporated for its
10:06:24 20 disclosure of pulsed inhalation device or pulsed dry powder
10:06:28 21 inhalers.

10:06:28 22 The same for *Roscigno*. If you look at the spec,
10:06:31 23 and we will look at the spec, how *Roscigno* is incorporated
10:06:35 24 into the patent, it is incorporated for its references to
10:06:37 25 inhalable composition. Again, it's not incorporated for an

10:06:41 1 example or an embodiment of a pulsed inhalation device or a
10:06:45 2 pulsed dry powder inhaler.

10:06:46 3 And, lastly, Figure 11. Figure 11 is, again, an
10:06:50 4 example of a dry powder inhaler. That is not a pulsed dry
10:06:53 5 powder inhaler. It's just an example of a dry powder
10:06:55 6 inhaler.

10:06:56 7 And as we've seen and as this Court has
10:06:59 8 recognized, the spec discusses both inhalation devices and
10:07:06 9 pulsed inhalation devices. The term "pulsed inhalation
10:07:10 10 devices" only comes up as we've already discussed in the
10:07:14 11 context of two dependent claims, 11 and 14. Claim 1 is not
10:07:18 12 limited to a pulsed inhalation device.

10:07:21 13 THE COURT: So just not to nitpick, but why do
10:07:28 14 you say limited to 11 and 14? Why isn't it also 12?

10:07:32 15 MR. DAVIES: To my knowledge, 11 and 14 are
10:07:34 16 asserted. I'm not sure whether 12 is or not.

10:07:38 17 Okay. So 11, 12 and 14, Your Honor. I
10:07:39 18 apologize.

10:07:40 19 THE COURT: No, it's all right.

10:07:41 20 MR. DAVIES: So going to this slide, as this
10:07:44 21 Court recognized when it denied the PI motion, the patentees
10:07:50 22 have not relied on any lexicography. And the spec only says
10:07:54 23 that dry powder inhalers may be pulsed. It doesn't say that
10:07:58 24 all are pulsed.

10:08:00 25 Therefore, UTC has this new argument where it

10:08:02 1 says it's not a lexicography argument anymore, it's an
10:08:05 2 embodiment. And as I already described, and we'll walk
10:08:08 3 through these portions of the spec, there are embodiments
10:08:10 4 but those embodiments --

10:08:11 5 THE COURT: And I'm sorry --

10:08:12 6 MR. DAVIES: Yeah, yeah.

10:08:12 7 THE COURT: -- Mr. Davies. When you say it's a
10:08:15 8 new argument because pulsed inhalation device is not defined
10:08:20 9 in the specification, I reread my preliminary injunction
10:08:26 10 opinion in the last 24 hours. Were they claiming it was
10:08:30 11 lexicography at the preliminary injunction? Because I
10:08:32 12 didn't see that in terms of --

10:08:34 13 MR. DAVIES: My understanding was they were
10:08:36 14 saying that it was defined in that way, and that the
10:08:38 15 argument during claim construction is now an embodiment
10:08:40 16 argument rather than an indefiniteness argument.

10:08:42 17 THE COURT: No, I understand this is embodiment.
10:08:43 18 But you're saying in the preliminary injunction stage, it
10:08:46 19 was lexicography?

10:08:48 20 MR. DAVIES: I'm -- Your Honor, if I got that
10:08:50 21 incorrect, I apologize.

10:08:51 22 THE COURT: I'm not -- I don't know. That's the
10:08:53 23 reason why I'm trying to --

10:08:54 24 MR. DAVIES: My remembrance was that it was, but
10:08:57 25 regardless, I think there's no disputing, given your

10:08:59 1 decision, there is no lexicography defining pulsed
10:09:02 2 inhalation devices.

10:09:03 3 THE COURT: All right. That's fine. Go ahead.

10:09:05 4 MR. DAVIES: We already talked about the claim,
10:09:07 5 so I'll skip over that.

10:09:09 6 Your Honor, the patent makes clear, again, that
10:09:12 7 the -- and the spec is directed to inhalation devices and
10:09:17 8 then only a subset of those are pulsed inhalation devices.
10:09:21 9 And this is a portion of the spec that I don't believe we
10:09:24 10 looked at with opposing counsel. But if you look at the
10:09:27 11 language here, it says, "pulsed inhalation devices are
10:09:30 12 disclosed." And then it describes -- it incorporates by
10:09:34 13 reference a number of specifications there.

10:09:36 14 And if we look to the disclosure of those that
10:09:39 15 are incorporated by reference specifically for, and I'll go
10:09:43 16 back to it, specifically as examples of pulsed inhalation
10:09:46 17 devices, all of these have examples of the Optineb-powered
10:09:53 18 nebulizer which is what Plaintiff's product, Tyvaso, was
10:09:56 19 approved for its use. So it's a powered device. It
10:09:59 20 provides puffs of the drug that the patient then inhales.

10:10:02 21 It's undisputed, again, but the Optineb device
10:10:06 22 is powered and that's how these pulses of drug are --

10:10:10 23 THE COURT: I'm sorry, Mr. Davies. Can you just
10:10:11 24 go back?

10:10:12 25 MR. DAVIES: Yes.

10:10:12 1 THE COURT: Where in the spec -- one more slide
10:10:14 2 back.

10:10:14 3 MR. DAVIES: Column 20.

10:10:16 4 THE COURT: This is 20.

10:10:17 5 MR. DAVIES: 44 to 57.

10:10:18 6 THE COURT: Please bear with me a minute.

10:10:20 7 Well, so that entire paragraph is littered with,
10:11:01 8 for example, may be. It basically doesn't exclude anything;
10:11:08 9 right?

10:11:08 10 MR. DAVIES: Well, I would -- and, Your Honor,
10:11:10 11 maybe the best way to address this is let's look at the
10:11:13 12 difference between this disclosure, which is Column 20,
10:11:18 13 Lines 44 to 57 and then the disclosure that opposing counsel
10:11:24 14 has relied on here for *Guarneri*.

10:11:25 15 Okay. So, again, if we look at Column 20, Lines
10:11:29 16 44 to 57, it expressly says, when it's citing those things,
10:11:33 17 pulsed inhalation devices are disclosed. Not nebulizers.
10:11:37 18 Not dry powder inhalers. Pulsed inhalation devices are
10:11:40 19 disclosed, and then it incorporates those.

10:11:42 20 If you look at the citation here to *Guarneri*, it
10:11:46 21 doesn't say a pulsed dry powder inhaler is disclosed. It
10:11:50 22 doesn't say a pulsed inhalation device is disclosed. It
10:11:53 23 just says "a dry powder inhaler and a dry powder composition
10:11:58 24 or formulation comprising treprostinil is disclosed."

10:12:01 25 And that's --

10:12:02 1 THE COURT: So --

10:12:02 2 MR. DAVIES: Mm-hmm.

10:12:03 3 THE COURT: -- looking at the sentence before
10:12:05 4 that, it says, "In some embodiments the inhalation device,
10:12:12 5 such as a pulsed inhalation device, may be a dry powder
10:12:19 6 inhaler which may contain a dry powder composition" blah,
10:12:23 7 blah, blah. "For example, a dry powder inhaler comprising
10:12:30 8 treprostinil is disclosed in *Guarneri*."

10:12:33 9 Right?

10:12:34 10 MR. DAVIES: Correct, Your Honor. That's what
10:12:35 11 it says.

10:12:36 12 THE COURT: Which is then incorporated herein by
10:12:38 13 reference by its entirety. It kind of -- and I ask this
10:12:46 14 against sort of the backdrop of, you know, the way I
10:12:51 15 understand claim construction is that disclosing an example
10:13:13 16 is, generally speaking, good, positive evidence that
10:13:21 17 whatever the example is is included. Whereas, not
10:13:26 18 disclosing the example is, generally speaking, not very good
10:13:35 19 evidence that the example is not included and the sort of
10:13:37 20 thing that leads to the Federal Circuit saying, Don't import
10:13:42 21 the embodiments into the claims.

10:13:45 22 So if there's a sort of contest between their
10:13:51 23 excerpt from page or Column 21, Line 6 to 14 and your's at
10:13:59 24 Column 20, Lines 44 to 57, isn't theirs a lot more
10:14:03 25 compelling?

10:14:04 1 MR. DAVIES: Your Honor, I'm not quite sure what
10:14:06 2 you mean by the "contest." What I'm trying to draw a
10:14:11 3 distinction between is the way in which they have
10:14:13 4 incorporated these references. And we start from an
10:14:15 5 understanding that the specification includes both general
10:14:20 6 inhalation devices and then only a subset of those are
10:14:23 7 pulsed. We don't disagree that you could have a pulsed
10:14:26 8 inhalation device, but the examples and the embodiments in
10:14:32 9 *Roscigno* are not identified as a pulsed dry powder inhaler.
10:14:36 10 They're just identified as a dry powder inhaler that would
10:14:38 11 fall in the general inhalation devices that would be covered
10:14:41 12 by Claim 1 of this patent.

10:14:43 13 So it is an embodiment of the patent. It's just
10:14:45 14 not an embodiment of a pulsed inhalation device which is
10:14:48 15 only a subset of the inhalation devices that are described.

10:14:52 16 THE COURT: So the way I kind of read the flow
10:14:53 17 of Column 21, Lines 6 to 14 is inhalation devices, general
10:15:01 18 big category. Pulse inhalation devices, smaller big
10:15:06 19 category. Dry powder inhalers, smaller category yet again.
10:15:13 20 And then the dry powder inhalers include *Guarneri*, or
10:15:19 21 *Roscigno* or whatever that is, which includes non-force dry
10:15:25 22 powder inhalers.

10:15:25 23 So haven't they disclosed their pulsed
10:15:34 24 inhalation device including the *Guarneri* or *Roscigno*,
10:15:39 25 whichever, non-force device?

10:15:43 1 MR. DAVIES: I don't believe they have, Your
10:15:45 2 Honor. And I believe the distinction between the two, the
10:15:48 3 way they've done it in Column 20 where they have expressly
10:15:51 4 incorporated by reference four pulsed inhalation devices is
10:15:55 5 different than what they've done in 21. They didn't say
10:15:59 6 another pulsed inhalation device is the *Roscigno* reference.
10:16:03 7 A pulsed dry powder inhaler is the *Roscigno* reference. So I
10:16:07 8 do read it differently, Your Honor.

10:16:09 9 And I think the way in which they're reading it
10:16:11 10 goes against the plain and ordinary meaning that it's the
10:16:14 11 device that has to be pulsed. So if you're going to go
10:16:16 12 against that, to me you need -- you need a definition of
10:16:19 13 that language to me is not clear and convincing enough to
10:16:23 14 override the plain and ordinary meaning.

10:16:25 15 THE COURT: Well, so, okay. All right.

10:16:34 16 MR. DAVIES: Your Honor, this is the *Guarneri*
10:16:36 17 reference, and we already looked at this. And, again,
10:16:38 18 there's this distinction in *Guarneri* between dry powder
10:16:41 19 inhalers that are disclosed in *Guarneri*, which it is relied
10:16:45 20 on for versus the Optineb ultrasonic nebulizer, which is
10:16:50 21 also disclosed in *Guarneri*, which the parties do not dispute
10:16:52 22 is a pulsed device.

10:16:54 23 And, again, you have the contrast between the
10:16:56 24 breath-powered inhaler, which, in our opinion, is simply a
10:16:59 25 dry powder inhaler, which is simply an inhalation device as

1 of Claim 1 and not a pulsed inhalation device. So this
2 reference in *Guarneri* is completely consistent with the way
3 it's being relied on. The way it's being incorporated by
4 the spec, it's being incorporated as a dry powder inhaler as
5 a general inhalation device and not a pulsed inhalation
6 device.

7 We don't rely on the definition, the dictionary
8 definition for our term, but we believe it's consistent with
9 our construction. It is the device that is providing the
10 force. It is the device that is pulsed. It is not
11 sufficient that the patient is pulsed through breathing.

12 It's also consistent with the declaration of
13 Dr. Channick that was submitted in the PI briefing. And
14 this is around Paragraphs 147 to 153. He said, "In my
15 experience, pulsed inhalers are those where the device
16 generates a force to expel drug from the device. Medication
17 does not reach the patient through the force of the
18 patient's breathing alone, but rather the device itself
19 generates the same force."

20 So that's his understanding as a clinician in
21 the pH space. And our position, Your Honor, is there's no
22 definition in the patent. There is no definition in the
23 patent that would contradict that plain and ordinary
24 understanding.

25 Opposing counsel also pointed to *Roscigno* as an

10:18:27 1 example of a pulsed dry powder inhaler. But, again, if we
10:18:30 2 look at how *Roscigno* is actually cited to and incorporated
10:18:34 3 in the patent, it's relied on for its disclosure of
10:18:38 4 inhalable compositions. "Inhalable compositions
10:18:41 5 administered" may include any of those described in blah,
10:18:45 6 blah, blah, blah. And then you get down to the *Roscigno*
10:18:47 7 reference which is the PCT ending 993.

10:18:50 8 Again, it's not incorporated as a pulsed
10:18:54 9 inhalation device. It's not incorporated as a pulsed dry
10:18:58 10 powder inhaler. It's incorporated for its inhalable
10:19:02 11 compositions, generally.

10:19:03 12 If we look at Figure 11 in the patent, again,
10:19:10 13 Figure 11 does not refer to pulsed inhalation devices. So
10:19:15 14 if we look at Paragraph 11, as with *Guarneri*, it has
10:19:18 15 different disclosures for pulsed versus unpulsed. So
10:19:23 16 Paragraph 11 refers to an ultrasonic pulsed nebulization
10:19:27 17 delivery device.

10:19:28 18 And there's also Figure 11 that opposing counsel
10:19:31 19 pointed you to, which is a dry powder inhaler, which we say
10:19:34 20 is not pulsed. And, in fact, if you look at *Roscigno*, it's
10:19:39 21 never referred to as a pulsed dry powder inhaler. It is a
10:19:43 22 dry powder inhaler which is contrasted to the ultrasonic,
10:19:46 23 pulsed nebulization delivery device.

10:19:50 24 And, Your Honor, this was also in the briefing,
10:19:54 25 but the other big issue we have with opposing counsel's

10:20:00 1 construction is that under their construction it removes any
10:20:03 2 distinction between pulsed and non-pulsed in the context of
10:20:07 3 inhalation devices in that they equate a patient breathing
10:20:11 4 with a pulse. And our position is if a patient breathing is
10:20:15 5 enough to make it a pulsed inhalation device, then any
10:20:18 6 inhalation device can be a pulsed inhalation device.

10:20:21 7 And the spec makes clear that they are two
10:20:23 8 different categories. And, in fact, that pulsed inhalation
10:20:26 9 devices are only a subset of the more general inhalation
10:20:29 10 devices that are available.

10:20:30 11 Also, Dr. Nathan during his --

10:20:35 12 THE COURT: So --

10:20:36 13 MR. DAVIES: Yes.

10:20:36 14 THE COURT: -- what about what Mr. Jackson said
10:20:40 15 about the patient with the -- you know, I forget what he
10:20:45 16 called it, but, you know, somebody who's basically got like
10:20:49 17 an oxygen machine. Can that be pulsed or non-pulsed?

10:21:00 18 MR. DAVIES: Under the Defendant's construction,
10:21:03 19 I was expecting them to argue that that would be pulsed
10:21:06 20 because the drug that enters the mouth is actually dependent
10:21:09 21 on the patient breathing. If the patient has a breathing
10:21:12 22 tube in, then it's continuous delivery.

10:21:15 23 So we don't see that as a meaningful
10:21:17 24 distinction. It doesn't solve this problem that they've
10:21:19 25 created with breath being sufficient for the pulse.

10:21:23 1 So our opinion, Your Honor, is the
10:21:24 2 non-continuous part of the definition does not distinguish
10:21:28 3 between the two classes that are disclosed in the patent.

10:21:31 4 THE COURT: Where do you get the non-continuous
10:21:33 5 part from?

10:21:36 6 MR. DAVIES: The fact that it is pulsed, Your
10:21:38 7 Honor, and then the pulse needs to come from the device.
10:21:40 8 They allow for devices where the patient is pulsing.

10:21:44 9 THE COURT: So you agree with them that pulsed,
10:21:51 10 at a minimum, means non-continuous?

10:21:53 11 MR. DAVIES: Yes, Your Honor. Yes.

10:21:55 12 THE COURT: Okay.

10:21:57 13 MR. DAVIES: We believe, though, that if you
10:21:59 14 don't have the -- if you don't include the force
10:22:01 15 requirement, that the force for that non-continuous delivery
10:22:05 16 comes from the device, then it renders that distinction
10:22:08 17 meaningless. The device itself, it is a pulsed inhalation
10:22:13 18 device. It is not an inhalation device that is pulsed by a
10:22:16 19 patient's breath.

10:22:18 20 So our plain and ordinary reading of that term
10:22:20 21 is that the device itself has to be pulsed. The patient
10:22:23 22 doesn't magically create an otherwise unpulsed device and
10:22:27 23 make it pulsed.

10:22:29 24 THE COURT: Okay.

10:22:31 25 MR. DAVIES: So with that, Your Honor, it's our

10:22:36 1 position that pulsed inhalation device should be construed
10:22:40 2 consistent with its plain and ordinary meaning. There is no
10:22:42 3 definition in the spec that would contradict that. And, in
10:22:45 4 fact, the disclosures that they rely on, the *Guarneri*,
10:22:49 5 *Roscigno*, and Figure 11 of the '327 patent, none of them are
10:22:52 6 incorporated for a disclosure of a pulsed inhalation device
10:22:56 7 or a pulsed dry powder inhaler.

10:22:58 8 THE COURT: Do you think the term "inhalation
10:23:04 9 devices," does that only refer to devices that are -- well,
10:23:14 10 so I remember when my children were young and they used to
10:23:17 11 have diseases of one kind or another, we had a device that,
10:23:23 12 for lack of a better word, misted up the room with -- I
10:23:28 13 don't know. I think it probably had a lot of water in it to
10:23:30 14 help breathing or something like that.

10:23:32 15 Is that an inhalation device?

10:23:33 16 MR. DAVIES: That could be an inhalation device,
10:23:36 17 Your Honor. I don't know expressly which one you're
10:23:39 18 referring to, but I --

10:23:40 19 THE COURT: It's been a long time. And would
10:23:47 20 you say that was a pulsed inhalation device?

10:23:49 21 MR. DAVIES: It would depend on what the
10:23:51 22 delivery was. If the force was provided by the machine and
10:23:55 23 delivered in pulses to the patient, it was non-continuous.

10:23:58 24 THE COURT: Well, so imagine a child's bedroom,
10:24:02 25 and this is like in the corner of the bedroom kind of

10:24:05 1 blowing water vapor out into the air. The child's just
10:24:09 2 breathing on his or her own. Is that a pulsed inhalation
10:24:14 3 device?

10:24:15 4 MR. DAVIES: If the delivery is continuous, then
10:24:18 5 no, it is not because we believe it also has to be
10:24:21 6 non-continuous.

10:24:23 7 THE COURT: Okay. Anything else?

10:24:25 8 MR. DAVIES: No.

10:24:26 9 THE COURT: All right. Thank you.

10:24:28 10 MR. DAVIES: Thank you, Your Honor.

10:24:29 11 THE COURT: Mr. Jackson.

10:24:31 12 MR. JACKSON: I'm just going to come back to
10:24:37 13 this slide. I think you understand where I'm coming from,
10:24:40 14 and I don't want to waste the Court's time, unless the Court
10:24:43 15 has questions.

10:24:43 16 I think the basic difference is our view is
10:24:46 17 pulsed inhalation devices, there are two categories. Either
10:24:49 18 it's pulsed inhalation or continuous inhalation. And pulsed
10:24:54 19 inhalation just means it delivers a bolus. It delivers a
10:24:58 20 pulse.

10:24:59 21 And so a pulse gets delivered to -- if it's
10:25:03 22 through inhalation, right. It is the inhalation that is
10:25:07 23 pulsed by breathing it in or by the machine delivering it.
10:25:15 24 It's where it's -- but the force does not have to come from
10:25:18 25 the device itself, as we said in the spec or as we -- the

10:25:21 1 example we showed in the spec.

10:25:23 2 So unless the Court has questions.

10:25:27 3 THE COURT: Well, so I'm trying to recall.

10:25:34 4 Mr. Davies said, and I think it was in the briefing, too,
10:25:40 5 that your -- so I think they said your definition is too
10:25:53 6 broad because it erases the distinction between -- I think
10:26:07 7 between pulsed inhalation and just inhalation. But I take
10:26:13 8 it what you'd say is, no, you know, pulsed inhalation
10:26:29 9 includes any non-continuous device. If you want to break it
10:26:32 10 down to nebulizers, or dry powder inhalers or something
10:26:37 11 else, that's a further way you can break it down. But the
10:26:41 12 category of pulse inhalation devices is broad enough to
10:26:45 13 include all of those things.

10:26:47 14 MR. JACKSON: Correct. And with all due respect
10:26:49 15 to Mr. Davies, his characterization of my argument of our
10:26:54 16 stance is a strawman that they set up in order to knock
10:26:57 17 down. We were -- we've been clear that the pulsed
10:27:00 18 inhalation device is a -- it needs to deliver a pulse of the
10:27:04 19 given medicine or the given -- whatever it's delivering in a
10:27:08 20 pulse, right. It just can't be continuous.

10:27:10 21 That's why I said the cannula, the thing over
10:27:12 22 your nose, and it's constant oxygen. That's continuous, not
10:27:15 23 pulsed. So it's -- the only question -- the only debate
10:27:20 24 between the parties here is: Where does the force for that
10:27:22 25 thing have to come from? Where does the force for the pulse

10:27:25 1 that you're inhaling have to come from? Does it come only
10:27:28 2 from the device or can it come from the human? The examples
10:27:31 3 in the specification show it can come from the human by when
10:27:34 4 you breathe in.

10:27:35 5 THE COURT: Okay. Thank you.

10:27:37 6 MR. JACKSON: Thank you, Your Honor.

10:27:37 7 THE COURT: Do you have anything more,
10:27:40 8 Mr. Davies?

10:27:42 9 MR. DAVIES: The last thing I'll say, Your
10:28:03 10 Honor, is under their or at least our understanding of their
10:28:07 11 construction, there's no difference between a general DPI or
10:28:12 12 a DPI that's pulsed.

10:28:14 13 THE COURT: I'm sorry.

10:28:14 14 MR. DAVIES: A general dry powder inhaler.
10:28:14 15 Sorry.

10:28:14 16 THE COURT: Thank you.

10:28:19 17 MR. DAVIES: Under their construction, there
10:28:20 18 would be no difference between a dry powder inhaler and a
10:28:22 19 pulsed dry powder inhaler because they and their expert are
10:28:28 20 equating breaths with the pulse. So there's no distinction
10:28:30 21 between dry powder inhalers for those that would be pulsed
10:28:34 22 versus those that would not be pulsed under their
10:28:36 23 construction.

10:28:37 24 Our construction --

10:28:38 25 THE COURT: Yeah, but nobody's claiming a pulsed

10:28:40 1 dry powder inhaler, so why does that matter?

10:28:44 2 MR. DAVIES: Well, they are, Your Honor. They
10:28:45 3 are in Claim 14. It's the -- where the -- a claim -- method
10:28:59 4 of claim 11 where the pulsed inhalation device is a dry
10:29:02 5 powder inhaler.

10:29:02 6 THE COURT: No, but the way you were saying it,
10:29:04 7 what I meant is there's no claim that says the -- that has
10:29:15 8 the sort of phrase "pulsed dry powder inhaler" as opposed to
10:29:20 9 non-pulsed dry powder inhaler. So saying you can't tell the
10:29:28 10 difference between the two doesn't matter because nobody's
10:29:30 11 trying to tell the difference between the two.

10:29:32 12 MR. DAVIES: Well, as we looked at in the spec,
10:29:33 13 the spec refers to dry powder inhalers with no reference to
10:29:38 14 pulsed dry powder inhalers. Claim 1 is broader and does not
10:29:41 15 contain this limitation for pulsed inhalers. So in our
10:29:46 16 mind, there is a distinction that's important, Your Honor.

10:29:48 17 THE COURT: Okay. All right.

10:29:49 18 So let me just take a very short break here.
10:29:53 19 Don't go anywhere. We'll be right back.

10:29:55 20 (Recess was taken.)

10:34:12 21 THE CLERK: All rise.

10:34:23 22 THE COURT: Have a seat. So I have a question
10:34:28 23 which may or may not have something to do with what we're
10:34:32 24 actually doing here, but it is: With the dry powder
10:34:41 25 inhaler, is there basically a cartridge that has one dose?

10:34:48 1 You put the cartridge in. You inhale it. Then if you want
10:34:52 2 another one, you have to put another cartridge in and inhale
10:34:55 3 it.

10:34:56 4 And, you know, is that basically what we're
10:34:59 5 talking about?

10:35:00 6 MR. JACKSON: That's my understanding of -- for
10:35:04 7 example, our device that's in Figure 11 in the patent and
10:35:08 8 the device in *Roscigno*, I need to double-check before I
10:35:11 9 answer on *Guarneri*, but I believe that's the case in
10:35:14 10 *Guarneri* as well.

10:35:14 11 THE COURT: All right. Thank you.

10:35:15 12 MR. JACKSON: So, yes.

10:35:16 13 MR. DAVIES: For our device, it's -- Your Honor,
10:35:18 14 the dose is contained in a pill. You put that in. It's
10:35:21 15 punctured. And then it's the breath of the patient that
10:35:24 16 spins the pill and draws the -- pulls it out, provides the
10:35:28 17 force.

10:35:28 18 THE COURT: But is it one breath of the patient?

10:35:31 19 MR. DAVIES: Three.

10:35:33 20 MR. SUKDUANG: Up to three.

10:35:34 21 MR. DAVIES: Up to three.

10:35:34 22 THE COURT: Okay. And you say "up to three." I
10:35:38 23 mean, are the instructions do it three times?

10:35:41 24 MR. DAVIES: Three times, yes.

10:35:43 25 THE COURT: Okay.

10:35:46 1 MR. SUKDUANG: I'm sorry. One clarification,
10:35:48 2 and similar to their device, each capsule has one dose.

10:35:53 3 THE COURT: Right.

10:35:53 4 MR. SUKDUANG: It may take three breaths to get
10:35:56 5 the entire dose. But as you increase, you might need to
10:35:59 6 take two capsules. So you put one capsule in, breathe up to
10:36:02 7 three times. Take the capsule out, put another capsule in.
10:36:06 8 Breathe up to three times, take the capsule out. So the two
10:36:09 9 capsules combined might constitute one dose.

10:36:12 10 THE COURT: Okay. But the point of between
10:36:17 11 continuous and non-continuous is that unlike, say, the thing
10:36:24 12 where it's attached to your nose is you take the one dose
10:36:30 13 and then time passes before you take another dose; right,
10:36:34 14 even if you're doing two cartridges?

10:36:38 15 MR. JACKSON: Well, there are times when you can
10:36:39 16 have that cannula behind your nose. The constant oxygen,
10:36:42 17 for example. That's constant. That's continuous.

10:36:45 18 THE COURT: Right, right. But talking about
10:36:50 19 treprostiril that what makes it non-continuous is you do
10:36:53 20 your one dose, which may be one cartridge, may be two
10:36:57 21 cartridges, may be six breaths. But that's one dose. And
10:37:02 22 you've done that, and then you don't do it again for some
10:37:06 23 period of time that's probably hours at least and perhaps
10:37:12 24 24 hours, but some period of time; right?

10:37:14 25 MR. JACKSON: Yes, Your Honor.

10:37:15 1 THE COURT: Right?

10:37:15 2 MR. DAVIES: Correct, Your Honor. Yes.

10:37:17 3 THE COURT: Okay. All right.

10:37:19 4 Well, I think I know what I am probably going to
10:37:21 5 do about non-continuous "pulsed inhalation device," but I
10:37:29 6 think it's worthwhile putting it in writing. So I'm going
10:37:33 7 to take that under advisement, and we'll get you something
10:37:41 8 before too long.

10:37:42 9 When is the next scheduled event in this case
10:37:45 10 that involves me?

10:37:47 11 MR. SUKDUANG: Pretrial, we believe, Your Honor.

10:37:49 12 THE COURT: And when's that?

10:37:51 13 MR. SUKDUANG: I believe trial is
10:37:53 14 September 2025. Oh, I have the schedule. Yeah. So we have
10:37:57 15 the pretrial June 3, '25.

10:37:59 16 THE COURT: Okay.

10:38:00 17 MR. SUKDUANG: And trial June 23, '25.

10:38:04 18 THE COURT: Oh.

10:38:05 19 MR. SUKDUANG: And depending on whether Liquidia
10:38:12 20 gets to launch in May or not, that could change this,
10:38:16 21 depending on the parties' decision. It could change from a
10:38:20 22 bench to a jury if UTC ends up seeking monetary damages.
10:38:26 23 And then in that instance, if it switches to a jury,
10:38:31 24 Liquidia may seek or they may seek the right to file summary
10:38:36 25 judgment. Because as of right now, it is planned as a bench

10:38:40 1 trial, so there's no summary judgment.

10:38:42 2 So things could change depending on whether we
10:38:44 3 launch or not and whether damages are sought.

10:38:49 4 THE COURT: All right.

10:38:49 5 MR. SUKDUANG: But that's where we sit.

10:38:51 6 THE COURT: All right. I take it the Plaintiff
10:38:56 7 asked for a jury trial or somebody's asked for a jury trial
10:39:00 8 here?

10:39:01 9 MR. SUKDUANG: Not initially because there was
10:39:02 10 no damages. We weren't on the market when the case was
10:39:04 11 filed.

10:39:05 12 THE COURT: No, no. I understand that. So you
10:39:06 13 can get a jury trial even though you didn't ask for it at
10:39:09 14 the beginning?

10:39:10 15 MR. SUKDUANG: We may ask. The situation
10:39:12 16 changed. So we may not ask for a jury trial. But if
10:39:15 17 they're asking for monetary damages, we don't know if
10:39:17 18 they're going to ask for a jury trial.

10:39:19 19 THE COURT: Okay. Mr. Jackson.

10:39:21 20 MR. JACKSON: Yeah. I -- yes. We -- to the
10:39:25 21 degree they launch, we would seek a jury trial. And yes --

10:39:28 22 THE COURT: And did you ask for that in the
10:39:30 23 Complaint?

10:39:31 24 MR. JACKSON: I don't believe so because I think
10:39:34 25 at that point it was just a -- it was -- we didn't have a

10:39:37 1 right to it because there was no -- it was just, in essence,
10:39:41 2 a Hatch-Waxman.

10:39:42 3 THE COURT: Okay. All right.

10:39:44 4 MR. JACKSON: Can I just do one other
10:39:45 5 housekeeping thing?

10:39:47 6 THE COURT: Sure.

10:39:47 7 MR. JACKSON: You asked me earlier which claims
10:39:50 8 we're asserting, and I said all -- 11 through 14 for the
10:39:54 9 relevant claim. It turns out -- we agreed not 13 because
10:39:57 10 that was the nebulizer.

10:39:58 11 It turns out not 12. I went back, and
10:40:02 12 Mr. Sukduang and I conferred. And he's -- we are not
10:40:05 13 asserting 12. So it's just 11 and 14 for the purposes of
10:40:08 14 the "pulsed inhalation device" definition.

10:40:11 15 THE COURT: And but all the rest of the
10:40:13 16 claims -- so other than 12 and 13, you're still asserting
10:40:16 17 all the claims in the patent?

10:40:17 18 MR. JACKSON: I believe that's right. Yes.

10:40:19 19 THE COURT: Okay.

10:40:20 20 MR. JACKSON: Thank you, Your Honor.

10:40:20 21 THE COURT: Thank you for that. All right.

10:40:22 22 Well, like I said, I'll take it under advisement
10:40:24 23 and see you later.

10:40:26 24 ALL COUNSEL: Thank you, Your Honor.

10:40:30 25 (Court was recessed.)

1 I hereby certify the foregoing is a true and
2 accurate transcript from my stenographic notes in the
3 proceeding.

4 /s/ Heather M. Triozzi
5 Certified Merit and Real-Time Reporter
6 U.S. District Court
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